Caregiver-mediated exercises after stroke

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Summary

Stroke is the third most common cause of disability in the world. Effects of stroke vary from minor neurological symptoms to severe deficits, that can have a major impact on daily functioning and quality of life. Exercise training is an important part of the rehabilitation process after stroke. Meta analyses show that increased intensity of exercise training after stroke leads to better functional outcome for patients in terms of mobility and activities of daily living (ADL). One such way to increase this intensity of training, especially in times where resources (mostly staff) become increasingly scarce, is to involve caregivers in the training of stroke patients. Therefore, in Reade centre for rehabilitation and rheumatology, together with Amsterdam UMC location VUmc, a so-called 'caregiver-mediated exercises' (CME) program, with the acronym CARE4STROKE was developed. In CARE4STROKE the person with stroke performs exercises together with a caregiver in addition to the regular therapy. The program is supported by weekly sessions with a trained therapist. A caregiver is defined as someone close to the patient, who is willing and able to do exercises together with the patient, for example a partner, family member or friend. CME can take place in the hospital, rehabilitation centre or geriatric rehabilitation department of a nursing home as well as in the home situation.

CME have the potential to facilitate early supported discharge (ESD) to patients own home setting. Early supported discharge includes the transfer from an inpatient environment to a community setting combined with the continuation of therapy and support. CME is hypothesized to improve functional outcome and to reduce length of inpatient stay (LOS) by increasing intensity of training. LOS is an important contributor to costs after stroke, CME might therefore be a way to reduce costs of inpatient stay and rehabilitation after stroke. In addition, CME may smoothen the transition to the home situation because patient and caregiver are more aware of what the patient can and cannot do in terms of mobility. Finally, CME can provide the opportunity to continue exercise therapy at home.

The overall aim of this thesis was to study the use and effects of CME after stroke. An overview of the evidence for earlier developed CME-interventions by using systematic review methods was therefore made as a start. Thereafter, the treatment protocol for the CARE4STROKE intervention was described in more detail. The CARE4STROKE program was then studied in a randomized controlled (cost-)effectiveness trial with the primary outcome measures self-reported mobility and LOS. Finally, patients and caregivers were interviewed about their experiences with participating in the CARE4STROKE program.

In **chapter 2** the available evidence about CME is summarized in a systematic review with meta-analysis. Available literature until October 2015 was searched for randomized controlled trials which compared CME to usual care, no intervention or another intervention

as long as it was not caregiver mediated. We found nine trials about CME, aimed at improving motor function in people who have had a stroke. Six trials, with 333 patient-caregiver couples, could be included in the meta-analysis. Due to the variety of outcome measures and low methodological quality, summarizing and combining of data was possible for a limited number of studies. When pooling available data, very low to moderate quality evidence in favour of CME on standing balance, walking distance and quality of life was found. For hand function, measured with the Wolf Motor function test, a significant effect in favour of the control group post intervention was found (2 studies, low quality of evidence). We did not find significant summary effect sizes on outcome measures of basic (for example bathing and dressing) and extended ADL (focused on activities in the kitchen, gardening) and caregiver burden. In contrast to the primary analysis, sensitivity analysis of CME-core trials did show a significant effect on basic ADL post intervention in favour of CME. CME-core refers to trials in which CME was the only intervention in contrast to non-CME-core trials in which caregivers were used to provide another existing intervention. We concluded that there is very low to moderate quality of evidence that CME may be a valuable intervention to augment the pallet of therapeutic options after stroke. Included studies were small and heterogenous and future high-quality research focused on effectiveness and cost-effectiveness is necessary.

Using the available evidence, the aforementioned CARE4STROKE program was developed: A caregiver-mediated exercise intervention supported by e-health using a tablet-app and tele-rehabilitation. We expected these innovative tools to be feasible and both motivating and supportive for the patient-caregiver couple. The practical content of the program was developed in collaboration with physical and occupational therapists, physicians, rehabilitation scientists and patient-caregiver couples.

As outlined in **chapter 3** the CARE4STROKE program is an 8-week program in which a patient with stroke exercises with his or her caregiver. The TIDieR (Template of Intervention Description and Replication) checklist was used to describe the program in detail concerning content, timing and intensity of the program, participant screening and selection, and intervention procedures. The exercises and use of the video application are explained and the role of the caregiver and trained therapist is described. The TIDieR checklist made it possible to describe this complex rehabilitation intervention in such detail that others can replicate it.

The CARE4STROKE program was studied in a proof-of-concept randomized controlled trial (RCT). The design of the trial is described in **chapter 4**. The primary aim of the RCT was to evaluate the effects and cost-effectiveness of the CARE4STROKE program. Patients with stroke admitted to a hospital stroke unit, rehabilitation center or nursing home were

randomly assigned to either 8 weeks of the CARE4STROKE program in addition to usual care or to 8 weeks of usual care. Primary outcome measures of the trial were self-reported mobility, measured on the mobility domain of the Stroke Impact Scale (SIS 3.0), and LOS in rehabilitation centre or nursing home calculated from stroke onset. Secondary outcomes for the patient were the other domains of the Stroke Impact Scale. In addition, measurements for motor impairment, strength, walking ability, balance, mobility, (Extended) ADL, psychosocial functioning, self-efficacy, fatigue, health-related quality of life as recommended by treatment guidelines were used. For caregivers, experienced strain, psychosocial functioning and quality of life were measured. Outcomes were assessed at baseline, 8 (directly post intervention) and 12 weeks after randomization. We expected a significant reduction of five points (11%) on the SIS mobility domain in favour of the CARE4STROKE-intervention group. Including 10% dropouts we calculated that 66 participants were needed in the CARE4STROKE trial to achieve a sufficient statistical power of 80% using a significant alpha of $P<0.05$.

In **chapter 5** we described the results of the proof-of-concept randomized controlled trial. No between group differences were found for primary outcome measures SIS-mobility over 8 weeks ($P=0.233$) and 12 weeks ($P=0.958$), and LOS ($P=0.818$). We did find, however, a significant interaction effect, post intervention, for anxiety of the patient (β 1.87, SD 0.88; $P=0.034$) and depression of the caregiver (β 2.32, SD 0.77; $P=0.003$) in favour of the CARE4STROKE intervention group. Decreased anxiety of patients persisted at the 12-week follow-up (β 1.02, SD 0.40; $P=0.010$). In addition, this proof-of-concept trial did show that the CARE4STROKE program is feasible and safe to apply. Patients in the CARE4STROKE group exercised a median of 1190 minutes with a caregiver versus 480 minutes in the control group ($P=0.002$). However, total amount of exercise time (i.e. the time combined the patient exercised in therapy, with a caregiver, with a nurse and independently) did not significantly differ between intervention and control group. Our planned treatment contrast was therefore not fully reached.

The explorative qualitative study we performed alongside the CARE4STROKE trial is described in **chapter 6**. This study focused on how participants managed these exercises together. The research questions were: 1) How do the patient-caregiver couples exercise together? And 2) what does exercising together bring about, besides more hours of practice? Semi-structured interviews were conducted with seven patients and seven caregivers who participated in the CARE4STROKE intervention. The data were interpreted by using inductive thematic data analysis. Three different role-dynamics were found during caregiver-mediated exercises: 1) patient in control, 2) in concert, and 3) the caregiver as informal carer. In addition, three themes were identified about what exercising together brings about: a) tailor made exercises through active involvement, b) preparation for the home situation,

and c) opportunity to be involved. In conclusion, we can say that practicing together goes beyond just intensifying therapy. We advise participating staff in caregiver-mediated exercises to be aware of the role-dynamics and the effects this might have on patient or caregiver. In addition, these results show that caregiver-mediated exercises enhance individualization of the treatment plan and preparation for discharge from inpatient setting to the home situation.

Finally, in the general discussion (**chapter 7**) the main findings of chapters 2–6 are summarized. The discussion continues with a reflection on the results, recommendations for daily practice and recommendations for further research.

A key question is why our trial is neutral in terms of self-reported mobility and LOS? A first explanation might be lack of treatment contrast between experimental and control group with respect to treatment intensity. Another explanation could be that our primary outcome measures are not responsive enough for the therapy-induced improvements in this proof-of-concept trial with a limited number of participants. Although there was a trend towards significance with regard to SIS mobility suggesting that a larger sample may have turned our study from neutral to positive.

The favourable effects found on mood and qualitative data on transition from inpatient setting to the home situation suggest that CME might in the future fulfil a role as part of an early supported discharge intervention. CME could then provide the possibility of early discharge and good preparation combined with continuation of therapy and support in the home situation. We also argue that these positive effects justify proceeding with the concept of CME in a larger phase III or phase IV cost-effectiveness trial.

For future research we advise to use a cluster-randomized controlled trial design to overcome the problem of contamination (e.g. the possibility that patients in the control group copy the applied caregiver exercises). In addition, cost-effectiveness of e-health technology in combination of CME used to augment rehabilitation services should be studied further. To measure the effects of CME on psychosocial functioning and quality of transition from an inpatient setting to the home situation ('care transition') we advise to validate a measurement tool for this goal.

Concerning the development of future CME programs, we discussed a number of considerations: the dependency of CME on the availability of a caregiver, our advice to further explore the possibilities of CME in hospital and geriatric rehabilitation settings and the possibility to use CME in patients with other impairments after stroke or even other diagnosis.

Finally, we advise to study cross-cultural differences in the use of CME. At this moment, worldwide, CME programs exist that differ with regard to content, progressiveness and

purpose (in addition or as substitution of usual care). Knowledge exchange and examination of cross-cultural differences can support further development and implementation of CME.